



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,006	06/23/2004	Seiji Saito	028567-0132	2732

7590 05/02/2007
Foley & Lardner
3000 K Street, NW, Suite 500
P.O. Box 25696
Washington, DC 20007-8696

EXAMINER

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
----------	--------------

1631

MAIL DATE	DELIVERY MODE
-----------	---------------

05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,006

Applicant(s)

SAITO, SEIJI

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3, 4, 6, 7, 9, 10 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 5, 8, 11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/23/2004 and 03/08/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED OFFICE ACTION

Election/Restrictions

Applicant's election of Group II in the reply filed on 02/07/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the restriction set forth on 01/18/2007, claims 3, 9, and 12 were classified as belonging to either Group I or Group II (see page 2 of the Office action mailed 01/18/2007). Upon review of the amended claim set filed 06/23/2004, it is noted that claim 3 has been amended to only depend from claim 1 (drawn to the invention of Group I), claim 6 has been amended to only depend from claim 4 (drawn to the invention of Group I), claim 9 has been amended to only depend from claim 7 (drawn to the invention of Group I), and claim 12 has been amended to only depend from claim 10 (drawn to the invention of Group I). Therefore, instant claims 3, 9, and 12 are drawn only to the non-elected invention of Group I.

Claims 1, 3, 4, 6, 7, 9, 10, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/07/2007.

Claims 1-16 are pending. Claims 1, 3, 4, 6, 7, 9, 10, and 12 are withdrawn. Claims 2, 5, 8, 11, and 13-16 are under examination. Acknowledgement is also made of amendments to the instant specification and claims (see specification and claims filed 06/23/2004). Though applicants have not indicated support for said amendment from the originally filed disclosure, upon review said disclosure does provide sufficient written support for the amendment.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and /or amino acid sequences set forth in CFR § 1.821(a)(1) and (a)(2). See, for example, the target sequence [10] of Figure 1. However, this application fails to comply with the requirements of CFR § 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statement under CFR § 1.821(f) and (g), and SEQ ID numbers cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID numbers are not required in the Figures, *per se*, however, the corresponding SEQ ID numbers then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD_ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to

Art Unit: 1631

this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5, 8, 11, and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must predict an interaction site in a target protein based on a calculation of frustration of a local part of the primary sequence information of said target protein. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The disclosure teaches that primary sequence of a target protein is used by a plurality of fragment structure prediction to predict fragment structures of the target protein. The resulting predicted fragments structures are further compared to acquired tertiary data, a frustration calculation is performed for a local part of the primary sequence information of the target protein, and an interaction site is predicted based on said frustration calculation. The disclosure does not provide detailed guidance regarding how to accurately predict a "real world" protein or a fragment thereof from a calculation performed on a local part of the primary sequence information of a target protein.

c) The disclosure provides exemplary embodiments of using structure prediction programs to predict tertiary structure and comparing predicting tertiary structure to structures in a tertiary structure database. The disclosure does not provide any working example wherein a "real world" protein structure or fragment thereof was successfully predicted based on a calculation of frustration of a local part of the primary sequence information of said target protein.

d) The nature of the invention, prediction of protein tertiary structure from primary sequence information, is complex.

e) The prior art does not show that a tertiary structure of a protein or fragment thereof can be accurately or reliably predicted from primary sequence information.

Ginalksi et al. sets forth a summary and review of recent efforts to develop automated structure determination protocols and alternative models to assign folds using prediction algorithms (see Ginalksi et al., Abstract). Page 1874, col. 1, line 15 through coil 2, line 5 of Ginalski et al. states:

"Theoretically, it should be possible to deduce structure from sequence by accurate simulation of physical processes. We are very far from achieving this goal, and the methods of practical importance were traditionally based on the observation that proteins with similar sequences are structurally similar as well."

Ginalski et al. further teaches that protein prediction methods are still in their infancy and are not yet capable of generating meaningful protein models (see Ginalksi et al., page 1875, col. 2, lines 22-35).

f) The skill of those in the art of protein tertiary structure prediction is high.

g) The predictability of protein tertiary structure from primary sequence information is unknown in the prior art.

h) The claims are broad in that they are drawn to predicting any interaction site in any target protein.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the disclosure lacks clear evidence that the structure of a protein or fragment thereof can be predicted from primary sequence information. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior teaches the prediction of protein tertiary structure and predicted protein activity from primary sequence information is not known in the art.

Art Unit: 1631

Finally, said practitioner would turn to trial and error experimentation to determine a real world target protein actually have or maintain an active site derived from a predicted tertiary structure of a protein or fragment thereof. Such amounts to undue experimentation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 5, 8, 11, and 13-16 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 2, 5, 8, 11, and 13-16 are drawn to a method and the related apparatus, computer program, and computer readable medium for interaction site prediction. The process for interaction site prediction comprises the abstract process steps of an input step of primary sequence information on a target protein, an acquisition step of tertiary that acquires tertiary data of said target protein, a fragment structure program execution step, a prediction result comparison step, a frustration calculation step, and an interaction site prediction step and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447

Art Unit: 1631

(1999)). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

In determining if the application of a judicial exception produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a result to be "useful," the application of a judicial exception must produce a result that is specific, and substantial. For a result to be "concrete," the application of a judicial exception must have a result that is reproducible. For a result to be "tangible," the application of a judicial exception must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 2, 5, 8, 11, and 13-16 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the application of a judicial exception is outputted to a display, a user, a readily accessible memory or other computer on a network, or by including a physical transformation.

Regarding data structures representing descriptive material and computer programs, MPEP § 2106.01(I) states:

"Data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. See, e.g., *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer

Art Unit: 1631

software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.

Similarly, computer programs claimed as computer listings *per se*, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish claims that define descriptive material *per se* from claims that define statutory inventions."

Instant claims 8 and 15 are drawn to a program that is not disposed on a computer-readable medium and, therefore, reads on descriptive material, *per se*, that is not a statutory invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631

EDJ
04/27/2007